Exhibit 235

Bombshell Emails: CDC Pressured FDA to Authorize COVID Boosters without Clinical Trials
https://childrenshealthdefense.eu/eu-issues/bombshell-emails-cdc-pressured-fda-to-authorize-covid-boosters-without-clinical-trials/

Emails
https://www.judicialwatch.org/documents/jw-v-hhs-boosters-prod-4-00293/

10/27/22 • COVID › NEWS

Bombshell Emails: CDC Pressured FDA to Authorize COVID Boosters Without Clinical Trials

The Centers for Disease Control and Prevention pressured U.S. regulators to clear COVID-19 boosters without clinical trial data, according to emails obtained by Judicial Watch.

By The Epoch Times

15

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By Zachary Stieber

The Centers for Disease Control and Prevention (CDC) pressured U.S. regulators to clear COVID-19 boosters without clinical trial data, according to newly released emails.

CDC officials relayed to counterparts at the U.S. Food and Drug Administration (FDA) in early August 2021 that they wanted authorization for Moderna and Pfizer boosters as data began showing that the vaccines weren't working as well as initially promoted.

The conversation took place on a call that was described by Dr. Phil Krause, a top FDA official, to several other FDA workers.

"Take a deep breath before reading this next paragraph. On that call, the CDC evidently stated that they will assemble all the data they are aware of on third dosing in this setting and send it to us in the hope that we will (very soon) authorize the third dose for immunocompromised as part of the EUA," Krause wrote in the Aug. 5, 2021, email.

EUA stands for emergency use authorization.

All of the COVID-19 vaccines were authorized under emergency conditions at that time.

No boosters had been authorized and no clinical data were available for the boosters.

The emails show that "the CDC wanted the booster approved without a trial," Dr. Jay Bhattacharya, a professor of medicine at Stanford University, wrote on Twitter.

The CDC didn't respond to a request for comment.

Krause was responding to Doran Fink, who also works for the FDA's Center for Biologics Evaluation and Research, charged with evaluating vaccines.

Fink sent along a post that had been made to an infectious diseases forum regarding whether doctors should be giving additional vaccine doses to patients with compromised immune systems despite the lack of authorization.

> millions of doses of vaccine set to expire, you should do what you think is best for your patients.
>
> "I can't believe you would get pushback from anyone. Keep in mind, nearly everyone in this group is six to seven months out from the second dose of the vaccine and many have significant daily exposure to the virus."

Fink said the post "accurately reflects more widespread thinking that I am hearing in other forums as well," including among doctors who advise the CDC on vaccines.

"Providers are losing confidence in FDA/CDC to do the right thing for their patients," Fink said.

Less than two weeks later, the FDA authorized boosters for certain people, including immunocompromised persons.

The agency said that "a thorough review of the available data" concluded the group "may benefit" from a third dose.

The only data cited on efficacy were from two studies, one conducted by French researchers and another by Canadian researchers. Pfizer and Moderna hadn't completed trials.

"As we've previously stated, other individuals who are fully vaccinated are adequately protected and do not need an additional dose of COVID-19 vaccine at this time," Dr. Janet Woodcock, the FDA's top official said.

But just weeks later, Woodcock and Dr. Rochelle Walensky, the CDC's top official, signed onto a joint statement saying that vaccine protection was waning and that boosters "will be needed to maximize vaccine-induced protection and prolong its durability."

In September 2021, the FDA and CDC authorized Pfizer boosters for many other Americans. The authorization was expanded to Moderna and Johnson & Johnson shots, and virtually all other Americans, later in the year.

Krause and Dr. Marion Gruber resigned from their positions because of opposition to the booster strategy.

Judicial Watch obtained the newly published emails as part of ongoing litigation against the Biden administration for not properly responding to a Freedom of Information Act request.

An earlier tranche of emails showed that Gruber was "very concerned" in late August 2021 about pressure from companies such as Pfizer over vaccine authorization.

"We need to be given time to consider their data and cannot be pushed by these companies and, for that matter the Administration, who try to impose timeless [sic] that make no sense," Gruber wrote to Dr. Peter Marks, a top FDA official.

"These FDA records further document top officials' concerns about the controversial COVID-19 booster shots," Judicial Watch President Tom Fitton said in a statement.

"That it has taken months and a federal lawsuit to uncover this critical material is a scandal."

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Zachary Stieber covers U.S. and world news for The Epoch Times. He is based in Maryland.

SUGGEST A CORRECTION

U.S. FOOD & DRUG ADMINISTRATION

August 29, 2022

Via Email: mdiliberto@judicialwatch.org

Meredith Di Liberto
Judicial Watch, Inc.
425 Third Street, SW, Suite 800
Washington, DC 20024

Re: FDA FOIA Request 2021-5961; *Judicial Watch, Inc. v. HHS,* 22-cv-00293-APM

Dear Ms. Di Liberto,

Per the Joint Status Report dated March 25, 2022, attached please find our fourth partial response to the Freedom of Information Act (FOIA) request number **2021-5961** that is the subject of above-referenced matter.

Attached are 43 pages of records from the FDA's Center for Biologics Evaluation and Research (CBER) (Bates numbered FDA-CBER-2021-5961-0189 to -0231) some of which contain redactions.

We have withheld portions of pages under Exemption (b)(4), 5 U.S.C. § 552(b)(4). That exemption permits the withholding of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential.

In addition, we have withheld portions of pages under Exemption (b)(5), 5 U.S.C. § 552(b)(5). Exemption (b)(5) permits the withholding of inter-agency or intra-agency communications or records which are part of the deliberative process and pre-decisional. Disclosure of such material could inhibit the open and candid expression of opinions and diminish the quality of the decision-making process. In addition, this exemption permits the withholding of materials subject to the attorney-client privilege and/or attorney work product doctrine.

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 552(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

Please direct any questions regarding this response to Assistant United States Attorney Marcia Sowles of the Department of Justice, at (202) 514-4960 or Marcia.Sowles@usdoj.gov.

Sincerely,

Ricci J. Ward -S Digitally signed by Ricci J. Ward -S
Date: 2022.08.29 08:37:48 -04'00'

Ricci Ward for Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch
Division of Disclosure and Oversight Management
Office of Communication Outreach and Development
Center for Biologics Evaluation and Research

Attachments
cc:
Marcia Sowles, Federal Programs Branch, USDOJ (By email)
Joshua Davenport, Office of the Chief Counsel, FDA (By email)

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

From: Krause, Philip
To: Finn, Theresa
Cc: Pratt, Douglas R.
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research
Date: Wednesday, August 4, 2021 12:04:00 PM

I will bring it up this afternoon as an option that may require more discussion.

From: Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 12:01 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>
Cc: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Phil – I have meetings 12:30-2:30 and then from 3-5. We have a bunch of these queries but we are in a bind – (b) (5) . Thus, an IND is required.

Maybe we can get a verbal OK from (b) (5) .

Theresa

From: Krause, Philip <Philip.Krause@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 10:35 AM
To: Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Cc: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

But it doesn't sound like they actually want to do a study. They just want to vaccinate these people—if I am reading this correctly. The CDC EA IND (b) (5)

I don't know if OCC (b) (5)

So I think (b) (5)

I am on a call with Peter Marks and Amanda Cohen at CDC at 230, but have nonstop meetings

starting at 1. So maybe you and I could discuss before 1 and I could bring up the (b) (5) option with them.

From: Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 10:22 AM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>
Cc: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: FW: [EXTERNAL] Use of Covid-19 Vaccines in Research

Hi Phil,

Recall that we want to (b) (5) . But per OCC (b) (5)

Understandably, the PI is getting impatient. I suppose (b) (5) – but we are so slammed right now (b) (5)

Theresa

From: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 10:09 AM
To: Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Cc: Fink, Doran <Doran.Fink@fda.hhs.gov>; Prutzman, Kirk C <Kirk.Prutzman@fda.hhs.gov>
Subject: FW: [EXTERNAL] Use of Covid-19 Vaccines in Research

From: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 10:07 AM
To: Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: FW: [EXTERNAL] Use of Covid-19 Vaccines in Research

Any word on how to respond to these folks?

From: (b) (4)
Sent: Wednesday, August 4, 2021 9:43 AM
To: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>; (b) (4) ; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; (b) (4)
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Gemignani,

We currently have a few immune compromised patients in our ICU who were fully vaccinated. It is difficult to remain patient when we are on the front lines observing this happen. We would like to initiate a third dose boost as soon as possible on our most vulnerable patients.

Is there a way to expedite this request?

Appreciatively,
(b) (4)

From: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>
Sent: Wednesday, July 28, 2021 4:51 PM
To: (b) (4) ; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

[EXTERNAL]

Good afternoon (b) (4)

Thank you for your patience. We will respond to you and (b) (4) as soon as we have a final determination from CBER.

Kind regards,
Helen Gemignani

From: (b) (4)
Sent: Wednesday, July 28, 2021 3:22 PM
To: (b) (4) Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) >; Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Dear Dr. Gemignani,

Please provide any updates on consideration of our study.

Appreciatively,
(b) (4)

(b) (4)

From: (b) (4)
Sent: Monday, July 26, 2021 12:19 PM
To: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Dear Dr. Gemignani,

Thank you for confirming receipt of our materials. Please provide a status update and let us know if any additional information is needed.

Thanks,
(b) (4)

(b) (4)

From: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>
Sent: Tuesday, July 20, 2021 11:09 AM
To: (b) (4) McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

[EXTERNAL]

Thank you (b) (4). I confirm receipt of your supportive documentation attachment within your 16 July email.

We hope to respond to you within this week.

Helen

From: (b) (4)
Sent: Friday, July 16, 2021 12:39 PM
To: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>
Subject: FW: [EXTERNAL] Use of Covid-19 Vaccines in Research

Dear Drs. Gemignani and McVittie,

Per Dr. Nelle's out of office message, I am forwarding the following informal IND exemption determination request to you.

Please confirm receipt and let us know when we can anticipate hearing your determination.

Thanks,
(b) (4)

Dear Dr. Nelle,

On behalf of (b) (4), attached please find a description of her intended study. We are submitting to you for an informal determination of whether the IND exemption regulations (21 CFR 312.2(b)) apply per
Ms. Kallungal's recommendation, below. We have included a description of the study with a clearly identified study population and a discussion of the issues from our perspective.

Please confirm receipt and let us know when we can anticipate hearing your determination.

Thanks,
(b) (4)

(b) (4)

From: Kallungal, Beatrice <Beatrice.Kallungal@fda.hhs.gov>
Sent: Tuesday, July 13, 2021 12:55 PM
To: (b) (4)
Cc: Kallungal, Beatrice <Beatrice.Kallungal@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

[EXTERNAL]

Dear (b) (4)

The Office of Vaccines Research and Review (OVRR), CBER has provided the following responses to your questions:

1. Are there any restrictions on the EUA Covid-19 vaccines that preclude their use in research (e.g. a study of heterologous vaccine boost doses)?

Response: COVID-19 vaccines authorized for emergency use may be studied in clinical investigations.

2. Are the EUA vaccines considered "lawfully marketed" (21 CFR 312.2(b)) for the purposes of an IND exemption (though we anticipate it is likely that we would still file an IND based on other criteria)?

Response: Vaccines which are available under EUA may be considered "lawfully marketed" if used under the scope of authorization as described in the Letter of Authorization (LOA) for each product. If the product you intend to use in your clinical investigation is sourced from the US government for administration by vaccination providers, as described in the LOA, and the proposed use is to prevent COVID-19 in the age group for which the product is authorized, a proposed study may be considered for IND exemption under 21.CFR312.2(b), which pertains to lawfully marketed products.

You may wish to submit a brief description of your intended study for an informal determination of whether the IND exemption regulations of 21CFR312.2(b) may apply. Note that an important consideration is the possible risk to subjects so please clearly identify the intended study population and include a discussion of the issue from your perspective. You may submit this information via email to the Chief of the Review Management Support Branch in the Office of Vaccines Research and Review, Dr. Tim Nelle: Timothy.Nelle@fda.hhs.gov.

3. Assuming an IND is required, would the FDA require that CMC data (or a Letter of Authorization from the manufacturer) be submitted with the IND application (or are the EUA materials sufficient to address this)?

Response: Use under IND requires the submission of CMC information. This may be provided through a letter of authorization from the manufacturer. If the proposed investigation will use authorized vaccine and a LOA cannot be provided the IND sponsor can request a waiver of the requirement for CMC information as described in 21 CFR 312.10.

If you have any further questions regarding the use of authorized COVID-19 vaccines please contact please contact the Office of Communications, Outreach and

Development via email at Industry.Biologics@fda.hhs.gov, 240-402-8010, or 800-835-4709.

Regards,

Beatrice Kallungal, MS
Branch Chief
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation Research
U.S. Food and Drug Administration
Tel: 301 796 9304
Cell: 240 620 7733

From: Krause, Philip
To: Pratt, Douglas R.; Fink, Doran; Finn, Theresa
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research
Date: Thursday, August 5, 2021 2:05:00 PM

Right now it seems like a small number of sponsors. (b) (5)

From: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Sent: Thursday, August 5, 2021 1:43 PM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

To confirm: Are we ready for Helen to (b) (5)

From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Thursday, August 5, 2021 12:55 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Maybe CBER IOD could triage these too…though so much for that on the data to support EUA amendments, I'm already being bothered by NIAID about DVRPA working with them on submission of their preliminary study data for Moderna boosters after discussions between Peter and Robert Johnson.

From: Krause, Philip <Philip.Krause@fda.hhs.gov>
Sent: Thursday, August 05, 2021 12:52 PM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

I think (b) (5), but I don't want to overwhelm the review teams if that opens floodgates…

From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Thursday, August 5, 2021 12:06 PM
To: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Thanks Douglas, I had the same question.

From: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Sent: Thursday, August 05, 2021 12:06 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Is resolution imminent? A few investigators are still waiting on our determination. For these investigators does it make sense to (b) (5)

From: Krause, Philip <Philip.Krause@fda.hhs.gov>
Sent: Thursday, August 5, 2021 11:06 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

From my brief discussion with Peter this morning, after some calls with CDC and HHS last night, the problem is that the (b) (5)

Take a deep breath before reading this next paragraph. On that call, the CDC evidently stated that they will assemble all the data they are aware of on third dosing in this setting and send it to us in the hope that we will (very soon) authorize the third dose for immunocompromised as part of the EUA. Peter told me that CBER IOD will triage this—I told him I need to be cc:ed on any of these communications so we don't get blindsided, but that we also need to protect the review team. This is part of why (b) (5) thinks (b) (5) the BLA is approved.

From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Thursday, August 5, 2021 11:00 AM
To: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

FYI – below is an excerpted post from this morning to an infectious diseases message board, concerning additional doses in immunocompromised patients. I think it accurately reflects more widespread thinking that I am hearing in other forums as well (e.g., the ACIP workgroup). Providers are losing confidence in FDA/CDC to do the right thing for their patients, including that we can't give inquiring parties a straight answer about what they are allowed to do outside of IND.

Date: Tues 3 Aug 2021 10:25
From: Richard Nathan (b) (6)

Israel, France, Germany, France, Russia, Hungary, and the UK have announced 'booster' shots. Pfizer recommends it and I trust their guidance over the turmoil at our federal agencies. With millions of doses of vaccine set to expire, you should do what you think is best for your patients. I can't believe you would get pushback from anyone. Keep in mind, nearly everyone in this group is six to seven months out from the second dose of the vaccine and many have significant daily exposure to the virus.

The term booster is wrong in my opinion. We don't think of the third dose in other vaccines such as the Hepatitis B series as a booster. We should think of it as the correct dosing of an mRNA vaccine.

Richard Nathan
Idaho Falls, ID

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

From: Krause, Philip <Philip.Krause@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 10:35 AM
To: Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Cc: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

But it doesn't sound like they actually want to do a study. They just want to vaccinate these people—if I am reading this correctly. The CDC EA IND (b) (5)

I don't know if OCC (b) (5) .

So I think (b) (5)

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Hi Phil,

Recall that we want to (b) (5) . But per OCC (b) (5)

Understandably, the PI is getting impatient. I suppose (b) (5) – but we are so slammed right now (b) (5)

Theresa

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Any word on how to respond to these folks?

From: (b) (4)
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Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

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Is there a way to expedite this request?

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Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

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Good afternoon (b) (4) ,

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Kind regards,
Helen Gemignani

From: (b) (4)
Sent: Wednesday, July 28, 2021 3:22 PM
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Cc: (b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
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To: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Dear Dr. Gemignani,

Thank you for confirming receipt of our materials. Please provide a status update and let us know if any additional information is needed.

Thanks,
(b) (4)

(b) (4)

From: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>
Sent: Tuesday, July 20, 2021 11:09 AM
To: (b) (4) McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

[EXTERNAL]

Thank you (b) (4). I confirm receipt of your supportive documentation attachment within your 16 July email.

We hope to respond to you within this week.

Helen

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Dear Drs. Gemignani and McVittie,

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exemption determination request to you.

Please confirm receipt and let us know when we can anticipate hearing your determination.

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Dear Dr. Nelle,

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If you have any further questions regarding the use of authorized COVID-19 vaccines please contact please contact the Office of Communications, Outreach and Development via email at Industry.Biologics@fda.hhs.gov, 240-402-8010, or 800-835-4709.

Regards,

Beatrice Kallungal, MS
Branch Chief
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation Research
U.S. Food and Drug Administration
Tel: 301 796 9304
Cell: 240 620 7733

From: Krause, Philip
To: Fink, Doran; Pratt, Douglas R.; Finn, Theresa
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research
Date: Thursday, August 5, 2021 12:51:00 PM

I think (b) (5), but I don't want to overwhelm the review teams if that opens floodgates…

From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Thursday, August 5, 2021 12:06 PM
To: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Thanks Douglas, I had the same question.

From: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Sent: Thursday, August 05, 2021 12:06 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Is resolution imminent? A few investigators are still waiting on our determination. For these investigators does it make sense to (b) (5)

From: Krause, Philip <Philip.Krause@fda.hhs.gov>
Sent: Thursday, August 5, 2021 11:06 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

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Date: Tues 3 Aug 2021 10:25
From: Richard Nathan (b) (6)

Israel, France, Germany, France, Russia, Hungary, and the UK have announced 'booster' shots. Pfizer recommends it and I trust their guidance over the turmoil at our federal agencies. With millions of doses of vaccine set to expire, you should do what you think is best for your patients. I can't believe you would get pushback from anyone. Keep in mind, nearly everyone in this group is six to seven months out from the second dose of the vaccine and many have significant daily exposure to the virus.

The term booster is wrong in my opinion. We don't think of the third dose in other vaccines such as the Hepatitis B series as a booster. We should think of it as the correct dosing of an mRNA vaccine.

Richard Nathan
Idaho Falls, ID

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

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I don't know if OCC (b) (5)

So I think (b) (5)

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Theresa

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Any word on how to respond to these folks?

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Cc: (b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; (b) (4)
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Dear Dr. Gemignani,

We currently have a few immune compromised patients in our ICU who were fully vaccinated. It is difficult to remain patient when we are on the front lines observing this happen. We would like to initiate a third dose boost as soon as possible on our most vulnerable patients.

Is there a way to expedite this request?

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Response: Vaccines which are available under EUA may be considered “lawfully marketed” if used under the scope of authorization as described in the Letter of

Authorization (LOA) for each product. If the product you intend to use in your clinical investigation is sourced from the US government for administration by vaccination providers, as described in the LOA, and the proposed use is to prevent COVID-19 in the age group for which the product is authorized, a proposed study may be considered for IND exemption under 21.CFR312.2(b), which pertains to lawfully marketed products.

You may wish to submit a brief description of your intended study for an informal determination of whether the IND exemption regulations of 21CFR312.2(b) may apply. Note that an important consideration is the possible risk to subjects so please clearly identify the intended study population and include a discussion of the issue from your perspective. You may submit this information via email to the Chief of the Review Management Support Branch in the Office of Vaccines Research and Review, Dr. Tim Nelle: Timothy.Nelle@fda.hhs.gov.

3. Assuming an IND is required, would the FDA require that CMC data (or a Letter of Authorization from the manufacturer) be submitted with the IND application (or are the EUA materials sufficient to address this)?

Response: Use under IND requires the submission of CMC information. This may be provided through a letter of authorization from the manufacturer. If the proposed investigation will use authorized vaccine and a LOA cannot be provided the IND sponsor can request a waiver of the requirement for CMC information as described in 21 CFR 312.10.

If you have any further questions regarding the use of authorized COVID-19 vaccines please contact please contact the Office of Communications, Outreach and Development via email at Industry.Biologics@fda.hhs.gov, 240-402-8010, or 800-835-4709.

Regards,

Beatrice Kallungal, MS
Branch Chief
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation Research
U.S. Food and Drug Administration
Tel: 301 796 9304
Cell: 240 620 7733

original message. Please note, the recipient should check this email and any attachments for the presence of viruses. The organization accepts no liability for any damage caused by any virus transmitted by this email.
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From: Krause, Philip
To: Finn, Theresa
Cc: Pratt, Douglas R.
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research
Date: Wednesday, August 4, 2021 10:35:00 AM

But it doesn't sound like they actually want to do a study. They just want to vaccinate these people—if I am reading this correctly. The CDC EA IND (b) (5)

I don't know if OCC (b) (5)

So I think (b) (5)

I am on a call with Peter Marks and Amanda Cohen at CDC at 230, but have nonstop meetings starting at 1. So maybe you and I could discuss before 1 and I could bring up the (b) (5) option with them.

From: Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 10:22 AM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>
Cc: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: FW: [EXTERNAL] Use of Covid-19 Vaccines in Research

Hi Phil,

Recall that we want to (b) (5) . But per OCC (b) (5)

Understandably, the PI is getting impatient. I suppose (b) (5) – but we are so slammed right now (b) (5)

Theresa

From: Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 10:09 AM
To: Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Cc: Fink, Doran <Doran.Fink@fda.hhs.gov>; Prutzman, Kirk C <Kirk.Prutzman@fda.hhs.gov>
Subject: FW: [EXTERNAL] Use of Covid-19 Vaccines in Research

From: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>
Sent: Wednesday, August 4, 2021 10:07 AM
To: Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: FW: [EXTERNAL] Use of Covid-19 Vaccines in Research

Any word on how to respond to these folks?

From: (b) (4)
Sent: Wednesday, August 4, 2021 9:43 AM
To: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>; (b) (4) McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>; (b) (4)
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Dear Dr. Gemignani,

We currently have a few immune compromised patients in our ICU who were fully vaccinated. It is difficult to remain patient when we are on the front lines observing this happen. We would like to initiate a third dose boost as soon as possible on our most vulnerable patients.

Is there a way to expedite this request?

Appreciatively,
(b) (4)

(b) (4)

From: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>
Sent: Wednesday, July 28, 2021 4:51 PM
To: (b) (4) McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4); Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

[EXTERNAL]

Good afternoon (b) (4)

Thank you for your patience. We will respond to you and (b) (4) as soon as we have a final determination from CBER.

Kind regards,
Helen Gemignani

From: (b) (4)
Sent: Wednesday, July 28, 2021 3:22 PM
To: (b) (4) Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Dear Dr. Gemignani,

Please provide any updates on consideration of our study.

Appreciatively,
(b) (4)

(b) (4)

From: (b) (4)
Sent: Monday, July 26, 2021 12:19 PM
To: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) >; Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

Dear Dr. Gemignani,

Thank you for confirming receipt of our materials. Please provide a status update and let us know if any additional information is needed.

Thanks,
(b) (4)

From: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>
Sent: Tuesday, July 20, 2021 11:09 AM
To: (b) (4) McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>; Pratt, Douglas R. <Douglas.Pratt@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

[EXTERNAL]

Thank you (b) (4). I confirm receipt of your supportive documentation

attachment within your 16 July email.

We hope to respond to you within this week.

Helen

From: (b) (4)
Sent: Friday, July 16, 2021 12:39 PM
To: Gemignani, Helen S <Helen.Gemignani@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Cc: (b) (4) Nelle, Timothy <Timothy.Nelle@fda.hhs.gov>
Subject: FW: [EXTERNAL] Use of Covid-19 Vaccines in Research

Dear Drs. Gemignani and McVittie,

Per Dr. Nelle's out of office message, I am forwarding the following informal IND exemption determination request to you.

Please confirm receipt and let us know when we can anticipate hearing your determination.

Thanks,
(b) (4)

Dear Dr. Nelle,

On behalf of (b) (4) attached please find a description of her intended study. We are submitting to you for an informal determination of whether the IND exemption regulations (21 CFR 312.2(b)) apply per
Ms. Kallungal's recommendation, below. We have included a description of the study with a clearly identified study population and a discussion of the issues from our perspective.

Please confirm receipt and let us know when we can anticipate hearing your determination.

Thanks,
(b) (4)

(b) (4)

From: Kallungal, Beatrice <Beatrice.Kallungal@fda.hhs.gov>
Sent: Tuesday, July 13, 2021 12:55 PM
To: (b) (4)
Cc: Kallungal, Beatrice <Beatrice.Kallungal@fda.hhs.gov>
Subject: RE: [EXTERNAL] Use of Covid-19 Vaccines in Research

[EXTERNAL]

Dear (b) (4)

The Office of Vaccines Research and Review (OVRR), CBER has provided the following responses to your questions:

1. Are there any restrictions on the EUA Covid-19 vaccines that preclude their use in research (e.g. a study of heterologous vaccine boost doses)?

Response: COVID-19 vaccines authorized for emergency use may be studied in clinical investigations.

2. Are the EUA vaccines considered "lawfully marketed" (21 CFR 312.2(b)) for the purposes of an IND exemption (though we anticipate it is likely that we would still file an IND based on other criteria)?

Response: Vaccines which are available under EUA may be considered "lawfully marketed" if used under the scope of authorization as described in the Letter of Authorization (LOA) for each product. If the product you intend to use in your clinical investigation is sourced from the US government for administration by vaccination providers, as described in the LOA, and the proposed use is to prevent COVID-19 in the age group for which the product is authorized, a proposed study may be considered for IND exemption under 21.CFR312.2(b), which pertains to lawfully marketed products.

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